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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/670,817	09/25/2003	Michael E. O'Donnell	22221/1210 (RU-339)	7755

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02/21/2007

EXAMINER

HUTSON, RICHARD G

ART UNIT

PAPER NUMBER

1652

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/21/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/670,817

Applicant(s)

O'DONNELL ET AL.

Examiner

Richard G. Hutson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 6-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 17-21 is/are allowed.
- 6) ☒ Claim(s) 1,2 and 6-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's cancellation of claims 3-5, amendment of claim 1 and the addition of new claims 10-21, in the paper of 11/17/2006, is acknowledged. Claims 1, 2, 6-21 are at issue and are present for examination.

Applicants' arguments filed on 11/17/2006, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Specification

The disclosure is objected to because of the following informalities:

Previously the instant specification was objected to because applicants claim that the instant application is a continuation of Application Serial Number: 09/716,964. This was objected to on the basis that the recitation in claims 1 and 5, "comprising at most about 0.9M sodium citrate buffer at a temperature of at least about 37°C" is not supported by the specification of Application Serial Number 09/716,964 and thus relative to the parent application would be considered new matter.

In response to this objection, applicants have amended claim 1 and cancelled claim 5 and argue that thus the objection is overcome by these amendments because the claim language is clearly supported by the first full paragraph on page 30, along with the nucleic acid sequence of SEQ ID NO: 175 and the corresponding amino acid sequence of SEQ ID NO: 176.

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Applicant's amendment of the claims and applicants complete argument is acknowledged however, is not found persuasive on the following basis. The previous and current objection is not directed to the claims, or based on new matter in the instant application, but rather it is directed to applicants claim that the instant application is a continuation of Application Serial Number: 09/716,964. Applicant's amendment of the claims and applicants pointing out of support in the instant application, does not show the support in the parent application, 09/716,964. Thus the objection is maintained, because that portion of applicants newly amended claim 1, which recites "hybridization conditions that are at least as stringent as the use of medium...", continues to not be supported by the specification of Application Serial Number 09/716,964 and thus **relative to the parent application** would be considered new matter.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2 and 6-16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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This rejection was stated in the previous office action as it applied to previous claim 1-9. In response to this rejection, applicants have amended claim 1, cancelled claims 3-5 and added new claims 10-21 and traverse the rejection as it applies to the newly amended claims.

Applicants traverse the rejection on the basis that the Federal Circuit has clearly espoused that per se conclusions of written description violations cannot be founded upon the basis of genus size alone. Applicants present Exhibits 1-3 as evidence that the nucleic acid sequence of SEQ ID NO: 175 and the corresponding amino acid sequence of SEQ ID NO: 176 represent the claimed genus. Applicants submit that Exhibits 1-3 present homologous Genbank accessions for *Bacillus* or *Geobacillus* *ssb* nucleic acids that are homologous to the nucleotide sequence of SEQ ID NO: 175, identified by BLAST search of the Genbank database and that these identified homologous sequences from various *Bacillus* species clearly share similar structure and therefore function.

Applicants submit that the language recited in claims 1 and 9 is precisely the type of claim language that was acknowledged in *Univ. of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997) as being acceptable under the written description requirement.

Applicants submit that the functional language should be acceptable when the genus as claimed is sufficiently limited in scope (i.e. from *Bacillus*) and the specification describes one or more species within that genus. Applicants submit claims 1 and 9

recite the same type of functional language that was identified as acceptable in Eli Lilly given the description of a single species by its nucleotide sequence.

Applicants further submit that the "Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112 first paragraph 'Written Description' Requirement" make explicitly clear that the description of a representative number of species does not require the description to be of such a nature that it would provide support for each species that the genus embraces.

Applicants further submit that the conclusion by the PTO is contrary to the evidence submitted herewith by applicants, as demonstrated by Exhibits 1-3.

Applicants thus submit that the rejection of the claims 1-9 is improper and should be withdrawn.

Applicant's complete traversal is acknowledged and has been carefully considered, however, is found non-persuasive for all the reasons previously made of record and repeated herein.

As previously stated, claims 1, 2, 6-9 continue to be directed to all possible isolated DNA molecules from any *Bacillus* species encoding a single-strand binding protein wherein said DNA molecule hybridizes to the complement of SEQ ID NO: 175, under conditions that are at least as stringent as use of a medium comprising 0.9M sodium citrate buffer at a temperature of 37°C. The specification, however, only provides a single representative species isolated from *Bacillus stearothermophilus* comprising the complete nucleotide sequence of SEQ ID NO: 175, encompassed by these claims. There is no disclosure of any particular structure to function/activity

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relationship in the single disclosed species. This is especially true for those DNA molecules that merely encode a "single strand binding protein". While it is true that written description violations cannot be founded upon the basis of genus size alone, the size of applicants claimed genus in combination with the limited number of species disclosed and the relationship between the structure of the claimed genus and the necessary functional limitations of the members of the claimed genus (i.e. encoding a single-strand binding protein) remains insufficient to adequately describe the breadth of the claimed genus. The specification also fails to describe additional representative species of these enzymes by any identifying structural characteristics or properties other than the activities recited in claim 1, for which no predictability of structure is apparent. Such remains, in spite of applicants submitted Exhibits 1-3, which while each sharing homology to the disclosed SEQ ID NO: 175, are insufficient to describe those members of the species with the required function. The functional language used is insufficient given the breadth of the claimed genus and the variation of the structures encompassed by the claimed genus.

While the "Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112 first paragraph 'Written Description' Requirement" make explicitly clear that the description of a representative number of species does not require the description to be of such a nature that it would provide support for each species that the genus embraces, it does require that sufficient description be made such that one of skill in the art would recognize that applicants were in possession of the claimed genus. This may

be done by various means other than the listing of encompassed species, however, it remains that applicants have not described the claimed genus sufficiently.

Given this lack of additional representative species or other descriptive support, as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 1, 2 and 6-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated DNA molecule encoding a single-strand binding protein, comprising the nucleotide sequence of SEQ ID NO: 175, does not reasonably provide enablement for any DNA molecule encoding a single-strand binding protein from any *Bacillus* species, hybridizing to the complement of SEQ ID NO: 175 under conditions that are at least as stringent as the use of a medium comprising 0.9M sodium citrate buffer at a temperature of 37°C. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

This rejection was stated in the previous office action as it applied to previous claim 1-9. In response to this rejection, applicants have amended claim 1, cancelled

claims 3-5 and added new claims 10-21 and traverse the rejection as it applies to the newly amended claims.

Applicants traverse the rejection on the basis that all that is needed is objective enablement of what is claimed and the present application provides the nucleotide sequence of *Bacillus stearothermophilus* ssb (e.g. SEQ ID NO: 175) and describes how one of ordinary skill can isolate homologs of the disclosed sequence.

Applicant's complete argument is acknowledged and has been carefully considered, however, is found nonpersuasive for the reasons previously stated and those repeated herein.

The claims continue to be so broad as to encompass any DNA molecule encoding a single-strand binding protein from any *Bacillus* species, hybridizing to the complement of SEQ ID NO: 175, under conditions that are at least as stringent as the use of a medium comprising 0.9M sodium citrate buffer at a temperature of 37°C. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of DNA molecules broadly encompassed by the claims. While applicants argue that they have provided the nucleotide sequence of *Bacillus stearothermophilus* ssb (i.e. SEQ ID NO: 175) and describe how one of ordinary skill can isolate homologs of the disclosed sequence and test the encoded SSB protein for activity, it remains unclear as to what activity applicants would screen for, and absent guidance as to which of those molecules encompassed by the structural limits have the desired activity, applicants have not enabled the claimed genus.

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While recombinant and screening techniques are known, it is not routine in the art to screen for multiple variants, as encompassed by the instant claims having an undefined activity. Guidance as to those molecules encompassing the functional limitations remains unclear. It is noted that the referred to Examples 26 and 30 to which applicants refer to in addressing testing of the encoded SSB protein for activity are unclear as to "the activity" applicants are testing for.

The specification does not support the broad scope of the claims which encompass all modifications and fragments of any DNA molecule encoding a single-strand binding protein from any *Bacillus* species having the undefined activity, because the specification does not establish: (A) regions of the DNA and encoded protein structure which may be modified without effecting the desired activity; (B) the general tolerance of single-strand binding protein and encoding DNA to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any amino acid residue and the encoding nucleotide sequence of a single-strand binding protein with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Because of this lack of guidance, the extended experimentation that would be required to determine which of the encompassed molecules have the desired the single-strand binding protein activity and the fact that the relationship between the sequence of a peptide and its tertiary structure (i.e. its activity) are not well understood and are not predictable, it remains that it would require undue experimentation for one skilled in the

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art to arrive at the majority of those DNA molecules of the claimed genus encoding a protein having the desired single-strand binding protein activity.

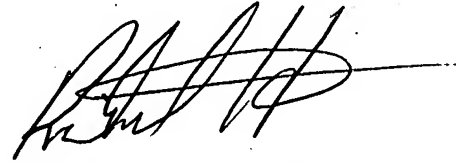
Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any DNA molecule encoding a single-strand binding protein from any *Bacillus* species, hybridizing to the complement of SEQ ID NO: 175 under conditions that are as stringent as use of a medium comprising 0.9M sodium citrate buffer at a temperature of 37°C. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of those DNA molecules having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G. Hutson whose telephone number is 571-272-0930. The examiner can normally be reached on M-F, 7:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'R. G. Hutson', with a long horizontal line extending to the right.

Richard G Hutson, Ph.D.
Primary Examiner
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rg
1/18/2006